

Protecting and Improving the Health of Iowans

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COVID-19 Vaccine Information Brief

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Changes to the document from the previous version are highlighted in yellow.

IMPORTANT/NEW COVID-19 Vaccine Information

- Updated COVID-19 Vaccine Resources
- Pfizer Tris COVID-19 Vaccine
- Moderna Label Update
- IRIS COVID-19 Provider Vaccine Inventory Management
- CDC Guidance on Storage & Handling
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- Pfizer Shelf-Life Extension Approved
- Vaccination Supplies
- Vaccine Expiration Date Resources
- V-Safe After Vaccination Health Checker

Updated COVID-19 Vaccine Resources

- CDC Endorses ACIP's Updated COVID-19 Vaccine Recommendations
- CDC Expands COVID-19 Booster Recommendations to 16-and-17-year-olds
- COVID-19 Vaccine Booster Shots
- COVID-19 Vaccines for Children and Teens
- COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy
 <u>Outcomes from COVID-19</u>: CDC strongly recommends <u>COVID-19 vaccination either before or during</u>
 <u>pregnancy because</u> the benefits of vaccination outweigh known or potential risks.
- Science Brief: Evidence Used to Update the List of Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19
- Quick Conversation Guide on COVID-19 Vaccines for Children
- Resources to Promote the COVID-19 Vaccine for Children & Teens
- <u>Using the COVID-Vac Tool to Assess Your COVID-19 Vaccination Clinic Staffing and Operations Needs</u>

IRIS COVID-19 Provider Vaccine Inventory Management

IRIS vaccine inventory management is a critical component of the pandemic vaccine response. All COVID-19 Vaccine Providers are required to report COVID-19 vaccine doses administered to IRIS which deducts from IRIS inventory. Maintaining accurate inventory impacts the state's ability to report accurate inventory to federal partners. Additionally, this also impacts the state's vaccine thresholds and the amount of vaccine available for all providers. Providers should make it a practice to regularly check inventory for expired vaccine and immediately remove expired inventory to prevent it from being administered. Please review these IRIS inventory management best practices to ensure accurate vaccine inventory.

- Ensure Vaccine Redistributions are accurately reported.
 - All COVID-19 vaccine transfers between providers MUST be completed and approved by IDPH.
 Please see the <u>Vaccine Redistribution Instructions</u>.
 - Providers should NOT physically transfer COVID-19 vaccine without prior IDPH approval.
- Verify all data entry in IRIS is up to date.
 - Doses administered are required to be reported to IRIS within 24 hours of vaccine administration.
- Verify data exchange between IRIS and the organization's Electronic Health Record (EHR) has worked appropriately.
 - IRIS Admin users can use the <u>Doses Not Deducted Report</u> to view and update doses of COVID-19 vaccines not deducted from IRIS inventory.
- Report vaccine wastage in IRIS.
 - Verify all vaccine wastage is documented appropriately using the approved adjustment reasons included in the Adjusting COVID-19 Vaccine Inventory for Wastage instructions.
 - VACCINE WASTAGE ADJUSTMENT REASONS CANNOT BE USED TO CORRECT VACCINE INVENTORY FOR UNACCOUNTED DOSES.

If you have questions regarding IRIS and vaccine inventory, contact the IRIS Help Desk at 1-800-374-3958.

Pfizer Tris COVID-19 Vaccine

Pfizer vaccine for adults/adolescents, known as Pfizer Tris, is available to Iowa healthcare providers. This vaccine is for individuals 12 years of age and older. This formulation has a distinctive **GRAY** cap:

- Available in smaller 300-dose configurations
- Does not require diluent
- May be stored at 2-8°C (36-46°F) for up to 10 week
- Can be used on individuals 12 years of age and older
- Shipping containers CANNOT be used to store this vaccine

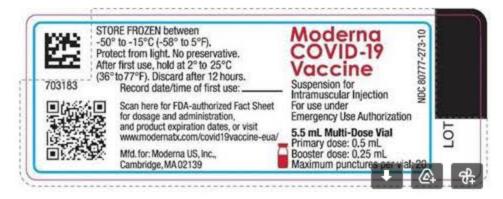
The Pfizer COVID-19 vaccine with the purple cap has been retired as of December 31, 2021. Healthcare providers should utilize existing Pfizer formulations (1170 and 450 dose packs) to the greatest extent possible. CDC recommends provider sites should ideally carry only one Pfizer adult formulation at a time. In order to avoid mistakes when both products may be in circulation, these products should not be offered/administered at the same time.

All Pfizer updated Fact Sheets may be found at:

- https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comir naty-and-pfizer-biontech-covid-19-vaccine#additional
- Healthcare Providers for 5-11 years of age, orange cap (must dilute) (fda.gov)
- Healthcare Providers for 12 years of age and older, gray cap (no dilution) (fda.gov)

COVID-19 Vaccine Presentations								
		Purple Cap	Gray Cap	Orange Cap				
	Age	12+	12+	5 - <12				
	Formulation	PBS / Sucrose	Tris / Sucrose*	Tris / Sucrose*				
	Diluent Required	YES (1.8mL)	NO (DO NOT DILUTE)	YES (1.3 mL)				
	Dosage	30 mcg	30 mcg	10 mcg				
	Doses per Vial	6 doses	6 doses	10 doses				
	Injection Volume	0.3 mL	0.3 mL	0.2 mL				
	Storage in ULT Freezer (-90°C to -60°C)	Up to 9 months	Up to 6 months*	Up to 6 months*				
	Storage in Refrigerator (2°C to 8°C)	Up to one month	Up to 10 weeks *	Up to 10 weeks*				
	Storage in Freezer (-25°C to -15°C)	Up to 2 weeks	N/A	N/A				

Moderna Label Update



FDA recently approved updates to both label and the EUA fact sheet for the Moderna COVID-19 vaccine. Distribution of the Moderna vials with the updated labels (see new label above) began during the week of January 13, 2021.

What has changed on the label of the Moderna COVID-19 vaccine:

- The label has been updated to indicate a volume of 5.5mL
- Doses for primary series and booster shots are now listed on the label
- Important reminder not to exceed a maximum of 20 punctures per vial

What remains the same for the Moderna COVID-19 vaccine:

- Formulation
- NDC [80777-273-99]
- Physical vial size
- Number of reportable doses
- Dose volumes (see below)
- Reporting requirements
- Wastage should continue to be reported based on 10 doses per vial

- Proper dosage of Moderna COVID-19 Vaccine
 - Primary series doses 1 and 2 dosage = 0.5 mL
 - Additional primary dose (3rd) dosage for immunocompromised persons = 0.5 mL
 - Booster dosage = 0.25 mL
- Each vial can ONLY be punctured up to 20 times.
 - Once the vial has reached the 20-puncture limit, the vial should be discarded even if there is vaccine remaining in the vial.IRIS vaccine inventory management is a critical component of the pandemic vaccine response. All COVID-19 Vaccine Providers are required to report COVID-19 vaccine doses administered to IRIS which deducts from IRIS inventory. Maintaining accurate inventory impacts the state's ability to report accurate inventory to federal partners. Additionally, this also impacts the state's vaccine thresholds and the amount of vaccine available for all providers. Please review these IRIS inventory management best practices to ensure accurate vaccine inventory.

For more information, please refer to the <u>EUA fact sheet</u> or <u>Administration Overview for Moderna COVID-19</u> Vaccine | CDC.

CDC Guidance on Storage & Handling

CDC provides guidance on the proper storage and handling of vaccine and tools for monitoring temperatures during transport and redistribution for each available vaccine.

- Pfizer: Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC
- Moderna: Administration Overview for Moderna COVID-19 Vaccine | CDC
- J&J/Janssen: Administration Overview for Johnson & Johnson's Janssen COVID-19 Vaccine | CDC

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

Pfizer Vaccines US Medical Affairs continues to host daily *Medical Updates & Immunization Site Training for All Providers with a Focus on Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine for Children 5 through 11 Years of Age.*

- In addition to Medical Updates, sessions will focus on the Storage, Handling, & Administration for currently available vaccine presentations
- These sessions will be updated to reflect new information and changes that evolve. Such updates will be identified at the start of each session and further explained during each presentation.

Please click on the links below to join the sessions at the designated times.*

Date & Time	Password	
Attendee link – Tuesday, February 01 – 3pm ET	yHaPhdmP332	
Attendee link – Wednesday, February 02 - 12pm ET	j3Hrm53J8uG	
Attendee link – Thursday, February 03 - 12pm ET	XxUF4Cg8Ma6	
Attendee link – Tuesday, February 8 - 3pm ET	VggmmC9dZ33	

Attendee link – Wednesday, February 9 - 12pm ET	xmPQNq7JJ32	
Attendee link – Thursday, February 10 - 12pm ET	deMyFdVJ465	

Pfizer Shelf-Life Extension Approved

FDA has approved a shelf-life extension for the Pfizer Pediatric vaccine (Orange cap, 5-11 YO, diluent required) and the soon to be available Adol/Adult Tris (Gray Cap, age 12+, no diluent). This approval may be found at Healthcare Providers for 5-11 years of age, orange cap (must dilute) (fda.gov); Healthcare Providers for 12 years of age and older, gray cap (no dilution) (fda.gov) and takes effect immediately. This extension applies to frozen (ULT) inventories only.

The date printed on the Pfizer Pediatric (orange cap) and Adult/Adolescent (gray cap, 12+, no diluent) vaccine vials indicate the manufacture date and NOT the expiration date. Originally, the expiration date was 6 months from the manufacture date. The expiration date for Pfizer orange and gray cap vaccine has now been extended to 9 months (while held at ULT frozen.) The Fact Sheets for both orange and gray cap vials provided by the FDA now reads, "regardless of storage conditions, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons". The updated expiry dates for both the orange and gray cap vials based on 9 months from the date of manufacture are provided below.

Printed Manufacturing Date	9-Month Expiry Date*
06/2021	Feb. 28, 2022
07/2021	Mar. 31, 2022
08/2021	Apr. 30, 2022
09/2021	May 31, 2022
10/2021	Jun. 30, 2022
11/2021	July. 31, 2022
12/2021	Aug. 31, 2022
01/2022	Sept. 30, 2022
02/2022	Oct. 31, 2022

^{*}Date of expiration always falls on the last day of the month

Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

Vaccination Supplies

The State of Iowa has recently obtained a limited quantity of individual 25 Gauge 5/8 inch safety needles, 1cc syringes, and a supply of combination 1 inch safety needles and 1 CC syringes. These vaccination supplies are available upon request by Local Public Health Agencies. These supplies are intended to be a back-up resource, the vaccine ancillary kits delivered with the vaccine will have 1 or $1^{1/2}$ inch needles, however IDPH is aware many prefer the 5/8 inch needles for the younger pediatric doses.

LPHAs should contact their <u>county emergency management coordinator</u> to request these supplies. County Emergency Managers will enter an individual WebEOC Mission for each LPHA requesting the needles and syringes.

Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. This is necessary for J&J vaccine as well as Moderna and Pfizer COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958.

For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of 12/31/2069 to serve as a <u>placeholder date</u>. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. It is important for healthcare providers to update vaccine expiration dates in IRIS.

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.jnj/

Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to www.modernatx.com/covid19vaccine-eua/

The new Pfizer Adult/Adolescent formulation (gray cap) and Pediatric COVID-19 vaccine (orange cap):

- Pfizer does not have an expiration date look up tool for these vaccines
- Formulation does NOT have expiration printed on vial
- Instead, each vial has the lot number and date of manufacture printed on the label
- Date on the label is NOT the expiration date
- Expiration date of the Pfizer pediatric COVID-19 vaccine is 6 months from the manufacturer date
 - Example: A vial with a manufacture date of 8/2021 includes August. It does not start in September. Expiration date would be Jan 31, 2022.

CDC's <u>COVID-19 Vaccine Expiration Date Tracking Tool</u> can help providers keep track of the expiration date by lot number.

J&J/Janssen	Moderna		Pfizer	
Lot Number Expiration	Lot Number	Expiration	Lot Number Ex	piration
1822786 2/6/2022	039D21A	2/1/2022	FC3180	1/31/2022
1822809 3/7/2022	939908	2/1/2022	FD8448	1/31/2022
215C21A 3/8/2022	065F21A	2/4/2022	EY0584	1/31/2022
1822811 3/20/2022	058F21A	2/5/2022	FC3184	1/31/2022
203F21A 3/21/2022	042D21A	2/7/2022	FA7485	1/31/2022
204F21A 3/22/2022	069F21A	2/7/2022	FC3183	1/31/2022
218C21A 4/9/2022	939909	2/8/2022	FD0809	1/31/2022
1855194 4/9/2022	043D21A	2/9/2022	FC3182	1/31/2022
211D21A 4/11/2022	044D21A	2/10/2022	FC3181	1/31/2022
213D21A 4/11/2022	045D21A	2/11/2022	FD0810	2/28/2022
220C21A 4/11/2022	091D21A	2/12/2022	30125BA	2/28/2022
1855191 4/11/2022	092D21A	2/13/2022	EY0581	2/28/2022
208D21A 4/24/2022	093D21A	2/14/2022	FD7220	2/28/2022
1855835 4/27/2022	085D21A	2/19/2022	EY0582	2/28/2022
1855190 4/27/2022	083F21B	2/20/2022	30135BA	2/28/2022
	939911	2/21/2022	FE3590	2/28/2022
	010G21B	2/21/2022	30145BA	2/28/2022
	939912	2/22/2022	FD7218	2/28/2022
	088D21A	2/25/2022	30130BA	2/28/2022
	015G21A	2/25/2022	FE3592	2/28/2022
			FE3594	2/28/2022

V-Safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: Posted on the Vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- V-safe after vaccination health checker website
- V-Safe Print Resources
- Vaccine Adverse Event Reporting System (VAERS)